STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
FACILITY LICENSING AND INVESTIGATIONS SECTION

IN RE: Stamford Hospital of Stamford, CT.
d/b/a The Stamford Hospital
30 Shelburne Road
Stamford, CT 06904

CONSENT ORDER

WHEREAS, The Stamford Hospital, (hereinafter the "Licensee"), has been issued License No.0059 to operate a General Hospital known as The Stamford Hospital, (hereinafter the "Facility") under Connecticut General Statutes Section 19a-490 by the Department of Public Health, State of Connecticut (hereinafter the "Department"); and

WHEREAS, the Facility Licensing and Investigations Section (hereinafter the "FLIS") of the Department conducted unannounced inspections on various dates commencing on December 22, 2008 up to and concluding on April 1, 2009; and

WHEREAS, the Department, during the course of the aforementioned inspections identified violations of the Connecticut General Statutes and/or Regulations of Connecticut State Agencies in a violation letter dated April 24, 2009 (Exhibit A – copy attached); and

WHEREAS, the Licensee is willing to enter into this Consent Order and agrees to the conditions set forth herein.

NOW THEREFORE, the FLIS of the Department acting herein and through Barbara Cass, Public Health Services Manager, and the Licensee, acting herein and through Brian G. Grissler its President and Chief Executive Officer (hereinafter the "CEO") hereby stipulate and agree as follows:

1. The Licensee shall execute a contract with an Independent Nurse Consultant (hereinafter the "INC") approved by the Department within two (2) weeks of the effective date of this Consent Order. The INC's duties shall be performed by a single individual unless otherwise approved by the Department. The Licensee shall incur the cost of the INC.

2. The INC shall function in accordance with the FLIS's INC Guidelines (Exhibit B - copy attached). The INC shall be a Registered Nurse who holds a current and unrestricted license in Connecticut. The Registered Nurse assuming the functions of the INC shall not be included in meeting the nurse staffing requirements of the Regulations of Connecticut State Agencies.
3. The INC shall act and perform the duties assigned herein at all times to serve the interest of the Department in assuring the safety, welfare and well-being of the patients and to secure compliance with applicable federal and state law and shall not accept any direction or suggestion from the Licensee or its employees that will deter or interfere in fulfilling this obligation.
4. Within forty-five (45) days of the effective date of this Consent Order, the INC shall conduct a comprehensive assessment of the following behavioral health services and infection control practices provided throughout the Facility:
    a. The behaviors leading to the use of physical and/or chemical restraints and/or seclusion at the Facility;
    b. Application of physical restraints in compliance with state and federal statutes and regulations at the Facility;
    c. The Facility's policies and procedures regarding use of restraints and/or seclusion;
    d. The Facility's education of staff in the use of restraints and/or seclusion in accordance with Facility policies and procedures;
    e. The Facility's review and revision of patient care plans to reflect the individual patient's problems, needs and goals, based upon the patient assessment and in accordance with applicable federal and state laws and regulations concerning the use of physical and/or chemical restraints and/or seclusion;
    f. The integration of behavioral health services and medical surgical services at the Facility for patients with acute mental status changes, including the need for consultation between the services, timeliness of consultations, implementation of recommendations made by the consulting service, and coordination of care; and
    g. The Facility's infection control programs for cleaning and maintaining perioperative areas (i.e., pre-operative, operating rooms and post-operative recovery areas) as well as segregating and disposing of non-sterile materials in these areas.

In performing the foregoing assessment, the INC shall be on-site at the Facility for not more than five (5) days.

5. Within forty-five (45) days of the effective date of this Consent Order, the INC shall submit to the Department a written report of the assessment conducted pursuant to paragraph 4, including, but not limited to, the Licensee's compliance with applicable federal and state statutes and regulations with regard to the matters set forth in paragraph 4, and identification of areas requiring remediation, if any.
6. In conducting the assessment and furnishing the written report referred to in paragraph 5 and in assessing the Licensee's compliance with applicable federal and state statutes and regulations with regard to the matters set forth in paragraph 4, the INC shall confer with the Licensee's Administrator/CEO, Executive Vice President and Chief Operating Officer, Senior Vice President of Medical Affairs and Chief Medical Officer, Senior Vice President of Patient Services and Chief Nursing Officer and Chief of Quality and Safety, and other staff necessary to the assessment of services provided.
7. The INC shall make recommendations to the Licensee's Administrator/CEO, Executive Vice President and Chief Operating Officer, Senior Vice President of Medical Affairs and Chief Medical Officer and Senior Vice President of Patient Services and Chief Nursing Officer and Chief of Quality and Safety for improvement in the delivery of direct patient care in the Facility with regard to the matters assessed in paragraph 4. If the INC and Licensee are unable to reach an agreement regarding the INC's recommendation(s), the Department, after meeting with the Licensee and the INC, shall make a final determination, which shall be binding on the Licensee.
8. The INC shall reassess and prepare a written report of the Facility's compliance with applicable federal and state law with regard to the matters set forth in paragraph 4 and progress in implementing any recommendations made as a result of the INC's initial assessment within sixty (60) days after furnishing the initial report referred in paragraph 5 and shall submit such report to the Department. In performing the foregoing reassessment, the INC shall be on-site at the Facility for not more than three (3) days unless the INC can show good cause, to be determined at the discretion of the Department, for why a longer time period is required.
9. Copies of all INC reports required by this Consent Order shall be simultaneously provided to the Administrator/Chief Executive Officer, Executive Vice President and Chief Operating

Officer, Senior Vice President of Medical Affairs and Chief Medical Officer, Senior Vice President of Patient Services and Chief Nursing Officer and Chief of Quality and Safety of the Licensee and the Department. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Order shall be made available to the Department, upon request.

10. The reports that the INC shall furnish under this Consent Order shall be limited to the initial assessment and reassessment written reports set forth in paragraph 5 and 8 of this Consent Order. If, upon the Department's review of the INC's second report prepared in accordance with paragraph 8, the Department is satisfied that the Licensee has complied with all applicable federal and state law with regard to the matters set forth in paragraph 4 and has made satisfactory progress in implementing any recommendations made as a result of the INC's initial assessment, then the Licensee may terminate its engagement of the INC. If the Department is not satisfied that the Licensee has complied with all the applicable federal and state laws with regards to the matters set forth in paragraph 4 after review of the INC's second report, then the Department may require that the Licensee's engagement of the INC be extended and further written reports be prepared by the INC until such compliance is attained.
11. Within fourteen (14) days of the effective date of this Consent Order, the Licensee shall develop and/or review and revise, as necessary, policies and procedures relative to:
    a. Patient specific interventions to be implemented prior to the utilization of mechanical and physical restraints and documentation of said interventions;
    b. Assessment for least restrictive restraint, specific types of restraints the institution shall utilize, physician orders for utilization of restraints, process for application, components of a patient assessment during the period a patient is in seclusion and/or restraints and documentation of said assessment;
    c. Restraint utilization in accordance with federal and state laws and regulations;
    d. The patient care plan process for utilization of mechanical and physical restraints and seclusion, to include, but not be limited to, the individual patient's problems, needs and goals, based upon the patient assessment and in accordance with applicable federal and state laws and regulations;

e. Infection control practices for cleaning and maintaining perioperative areas (i.e., pre-operative, operating rooms and post-operative recovery areas) as well as segregating and disposing of non-sterile materials in these areas; and

f. Environmental rounds in the perioperative areas.

12. The Licensee shall ensure that each patient who receives an as needed (PRN) Ativan and Haldol medication, is appropriately assessed prior to the administration of the medication for the purpose of determining the appropriateness of the administration of said medication and shall:

a. Develop guidelines for the administration of as needed (PRN) Ativan and Haldol medications, response to the medication and applicable documentation;

b. Conduct random weekly audits of the medical records of ten (10) patients to ensure that as needed (PRN) Ativan and Holdol medications are administered in accordance with physician orders, the plan of care and/or standards of practice;

c. The weekly audits conducted in accordance with subparagraph (b) above will be performed by a Pharmacist licensed in Connecticut who will review active medical records. This individual shall be responsible for timely notification of the attending physician and/or psychiatrist regarding any concerns, adverse effects or contraindications; and

d. The weekly audits conducted in accordance with subparagraph (b) above shall be performed for a period of one (1) year commencing on the effective date of this Consent Order and the documentation of said audits shall be maintained for a period of two (2) years after their completion.

13. Within sixty days (60) days of the effective date of this Consent Order all hospitalists, emergency department physicians, residents, psychiatrists, registered nurses and licensed practical nurses employed at the Facility shall receive education, as necessary, regarding the policies and procedures in paragraph 11. Members of the Facility's medical staff not covered by the first sentence of this paragraph 13 shall be notified of these policies and procedures through a written communication issued by the Senior Vice President and Chief Medical Officer within the same sixty (60) day period.

14. Within ninety (90) days of the effective date of this Consent Order, the Licensee, through a Pharmacist licensed in Connecticut, shall conduct an educational program for

all hospitalists, emergency department physicians, residents, psychiatrists, registered nurses and licensed practical nurses employed at the Facility relative to the appropriate utilization of as needed (PRN) Ativan and Haldol medications. Initial orientation to the Facility as a new employee shall also include this education. Members of the Facility's medical staff not covered by the first sentence of this paragraph 14 shall be notified of these policies and procedures through a written communication issued by the Senior Vice President and Chief Medical Officer within the same ninety (90) day period.

15. Within thirty (30) days of the effective date of this Consent Order, the Licensee shall review and revise, as appropriate, policies and procedures relative to the Licensee's clinical practice guidelines for the psychiatric behavioral health program and scope of practice to specifically address the collaborative practice of Advanced Practice Registered Nurses and/or Physicians' Assistants and Attending Physicians within the Facility. Any revisions to these policies and procedures shall be presented to the Medical Staff for approval.
16. The Licensee shall provide education for licensed independent practitioners focusing on the policies and procedures outlined in paragraph 15.
17. Within sixty (60) days of the effective date of this Consent Order, the Licensee shall incorporate into its Quality Assurance/Performance Improvement Program (QAPI) a method to monitor implementation of the requirements of the Consent Order and those recommendations implemented as a result of the INC assessment. A report on such measures shall be presented to Medical Staff and to the Governing Authority. The QAPI will include outcome measures, which identify and analyze the quality of health care for inpatients. Minutes of the QAPI meetings shall be kept for a minimum of three (3) years after the date of the meeting and made available for review upon request of the Department.
18. The Licensee shall designate one individual who shall assume the overall responsibility for full implementation of this Consent Order. The name of the designated individual shall be provided to the Department contemporaneous with the Licensee's execution of this Consent Order.
19. The individual assigned to oversee the implementation of the requirements of this document shall submit monthly reports to the Department regarding implementation of the Consent Order

components and shall meet with a Department representative every six (6) weeks for the first three (3) months after the execution of this Consent Order and thereafter at twelve (12) week intervals for the duration of the Consent Order. The meetings shall include discussions of issues related to the care and services provided by the Facility and the Facility's compliance with applicable federal and state statutes and regulations.

20. The Licensee shall pay a monetary penalty to the Department in the amount of four thousand dollars ($4,000.00), by money order or bank check payable to the Treasurer of the State of Connecticut and mailed to the Department within two (2) weeks of the effective date of this Consent Order. The money penalty and any reports required by this document shall be directed to:

Cheryl Theriault, RN, BSN
Supervising Nurse Consultant
Facility Licensing and Investigations Section
Department of Public Health
410 Capitol Avenue, P.O. Box 340308 MS #12HSR
Hartford, CT 06134-0308

21. All parties agree that this Consent Order is an Order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of the Consent Order or of any other statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, or any other administrative and judicial relief provided by law. This Consent Order may be admitted by the Department as evidence in any proceeding between the Department and the Licensee in which compliance with its terms is at issue. The Licensee retains all of its rights under applicable law.
22. The execution of this document has no bearing on any criminal liability without the written consent of the Director of the MFCU or the Bureau Chief of the Department of Criminal Justice's Statewide Prosecution Bureau.
23. The terms of this Consent Order shall remain in effect for a period of two (2) years from the effective date of this document unless otherwise specified in this document.
24. The Licensee understands that this Consent Order and the terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum including any right to review under the Uniform Administrative Procedure Act, Chapter 368a of the

Statutes, Regulations that exists at the time the agreement is executed or may become available in the future, provided that this stipulation shall not deprive the Licensee of any other rights that it may have under the laws of the State of Connecticut or of the United States.

25. Should the Licensee not be able to maintain substantial compliance with the requirements of the Consent Order, the Department retains the right to issue charges to encompass those identified in the April 24, 2009 violation letter referenced in this document.
26. The Licensee had the opportunity to consult with an attorney prior to the execution of this Consent Order.

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WITNESS WHEREOF, the parties hereto have caused this Consent Order to be executed by their respective officers and officials, which Consent Order is to be effective as of the later of the two dates noted below.

Stamford Hospital of Stamford, CT – Licensee

8/3/09
Date

By: _____
Brian G. Grissler, President/CEO

STATE OF Connecticut)

County of Fairfield) ss Stamford on 8/3/2009

Personally appeared the above named Brian Grissler and made oath to the truth of the statements contained herein.

My Commission Expires: 7/31/13
(If Notary Public)
IVETTE VALLEJO-MELENDEZ
NOTARY PUBLIC
MY COMMISSION EXPIRES JULY 31, 2013

Ivette Vallejo-Melendez
Notary Public [ ]
Justice of the Peace [ ]
Town Clerk [ ]
Commissioner of the Superior Court [ ]

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

8/3/09
WHF Date

By: Wendy H. Furniss
~~Barbara Cass, R.N.~~
~~Public Health Services Manager~~
~~Facility Licensing and Investigations Section~~

Wendy H. Furniss, RNC, M.S.
Chief, Healthcare Systems Branch

EXHIBIT A
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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

April 24, 2009

Brian Grissler, President & CEO
Stamford Hospital
30 Shelburne Road
P.O. Box 9317
Stamford, CT 06904

Dear Mr. Grissler:

Unannounced visits were made to Stamford Hospital commencing on December 22, 2008 and concluding on April 1, 2009, by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations, a substantial allegation survey and full federal survey at the request of CMS, a licensure renewal inspection and reviewing for the implementation of a plan of correction for a violation letter dated November 13, 2008 that was amended on January 27, 2009.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for May 20, 2009 at 10:00 AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish legal representation, please feel free to have an attorney accompany you to this meeting.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

- Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
- Date corrective measure will be effected.
- Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Ann Marie Montemerlo, R.N.
Supervising Nurse Consultant
Facility Licensing and Investigations Section

AMM:zbj

c. Director of Nurses
Medical Director
Complaints: CT #9075, CT #9027, CT #9103
CT #8800, CT #9240, CT #9029

Phone:
Telephone Device for the Deaf: (860) 509-7191
410 Capitol Avenue - MS # _____
P.O. Box 340308 Hartford, CT 06134

DATES OF VISITS: Commencing on December 22, 2008 and concluding on April 1, 2009.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following are violations of Connecticut General Statutes Section 46a-154 (d) (1) and/or (2) and/or the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2)(B) and/or (4)(A) and/or (d) Medical record (3) and/or (e) Nursing service (1) and/or (i) General (6).

1. Based a review of the medical record and review of hospital policy, the hospital failed to ensure that the Plan of Care for one patient, Patient #1, reflected the use of chemical and/or mechanical restraints based on assessment and evaluation of the patient. The finding includes:
    a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual hallucinations and with a sitter (1:1) assigned to continuously monitor the patient. Review of the clinical record during the period of 12/17/08 at 12:21 AM through 12/18/08 at 2 PM indicated that Patient #1 was restrained with soft bilateral wrist and ankle restraints that progressed to a vest restraint and four-point leather restraints when the patient attempted to elope from the hospital room and/or exhibited aggressive behavior. In addition, the patient received medication (Ativan and Haldol) to address the patient's behaviors of agitation and/or aggression. Review of the patient's care plan failed to address the use of mechanical and/or chemical restraints. Patient #1, although in four-point leather restraints and restraint vest, removed himself/herself from the restraints twice (in quick succession) between 1:40 PM and 2 PM on 12/18/08 and jumped through a closed, third story window with injuries that included a traumatic subarachnoid hemorrhage, pulmonary contusion, multiple fractured ribs and spinal vertebrae, pneumothorax, and fractured scapula.

2. * Based on observation, review of medical records, review of hospital policy and interview with facility personnel, the hospital failed to ensure that restraints utilized for two (2) of five (5) patients reviewed (Patients #1 and #2) were properly applied to ensure the patient's safety. The findings include:
    a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual hallucinations and with a sitter (1:1) assigned to continuously monitor the patient. Review of the clinical record dated 12/17/08 at 12:21 AM identified that Patient #1 was physically held by the security officer after attempting to elope from the hospital room and was placed in a vest restraint and 4-point soft bilateral wrist and ankle restraints. On 12/18/08 at approximately 12:30 AM, Patient #1 removed both wrist restraints in the presence of the 1:1 sitter. A vest restraint and 4-point soft restraints were subsequently applied. At approximately 5 AM on 12/18/08, Patient #1 removed all restraints in the presence of the 1:1 sitter and was observed to be extremely combative. A vest restraint was reapplied and leather 4-point restraints were initiated. At approximately 1:10 PM on 12/18/08, Patient #1, in the presence of a 1:1 sitter, removed all 4-point leather restraints. During interview on

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

12/30/08, Sitter #2 stated that Patient #1, despite wearing the vest restraint, sat upright in bed, bent at the waist and used his/her teeth to untie one wrist then ultimately, untied his/her other wrist and ankle restraints. During interview on 12/30/08, RN #1 observed that the ties to the vest restraint stretched as the patient leaned forward. Security was called and the patient was again restrained with a vest restraint and 4-point leather restraints. At approximately 1:45 PM on 12/18/08, Patient #1 removed all restraints for a fourth time in the same manner as described previously. Sitter #1 stated during interview on 12/23/08 that Patient #1 slid down in bed and took off the leather restraint of one wrist with his/her teeth, removed all restraints, including the vest, which was attached to the bed frame at the edge of the mattress with a quick release knot. Although staff members responded to Patient #1's room, the patient moved past all staff, ran down the hallway and subsequently jumped through a closed third story window. Review of the manufacturer's directions identified that the vest restraint was contraindicated for combative patients. Review of hospital's Restraint policy failed to identify hospital approved devices and/or direction for the application of restraint devices. The hospital failed to ensure that appropriate restraints were utilized and/or properly applied to ensure the patient's safety.

b. Surveyor observation on 12/30/08 identified that Patient #2 was orally intubated, turned to his/her right side and had his/her right wrist restraint tied to the bedrail. During interview on 12/30/08, the Clinical Educator stated that she had spoken to the RN caring for the patient who identified that the Resident (physician) had tied the wrist restraint to the bedrail. Review of the facility policy for Use of Restraint and/or Seclusion directed that restraints should never be fastened to the siderail. During interview on 1/20/08, the Manager of Regulatory Affairs stated that although physicians received a packet of information during general hospital orientation and/or credentialing, no formal program existed for the education of physicians in the ordering and/or use of restraints.

3. * Based on a review of the medical record and review of hospital policy, the hospital failed to ensure that physician orders were obtained for the use of a vest and/or four-point leather restraints that were applied to one patient (Patient #1). The findings include:
   a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual hallucinations and with a sitter (1:1) assigned to continuously monitor the patient. Review of a physician's order dated 12/17/08 at 12:21AM directed that soft bilateral wrist and ankle restraints be applied when the patient attempted to elope from the hospital room. Review of the medical record identified that in addition to the application of soft four-point restraints, staff had also applied a vest restraint. On 12/18/08 at approximately 5 AM, a vest restraint and four-point leather restraints were implemented without a physician order when the patient became extremely combative. Review of the hospital's Restraint policy failed to identify that a written physician order must be obtained at the time of the emergency application of restraints or immediately thereafter.

4. Based on review of the medical record and review of the hospital policy, the hospital failed to

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

ensure that the Attending physician was consulted when one patient (Patient #1) required restraints. The findings include:

a. Patient #1 was admitted to the hospitals medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual hallucinations. The patient was admitted by Hospitalist #1, who completed the History and Physical and identified that the patient required a 1:1 sitter and Ativan for anxiety and agitation. Review of the clinical record dated 12/17/08 at 12:21AM identified that Patient #1 attempted to elope from the hospital room, was physically held by security and placed in soft bilateral wrist and ankle restraints in accordance with Resident #1's order. Although Resident #1 directed the use of restraints, the medical record lacked evidence that the Attending physician (Hospitalist #1) was consulted as soon as possible of the patient's behavior and need for restraints. Review of the hospital's Restraint policy identified that the Attending physician must be notified of the patient's need for restraint.

5. Based on review of six (6) medical records of patient's utilizing restraints and review of hospital policy, for one patient (Patient #1), the hospital failed to ensure that the restraint orders were renewed every four (4) hours in accordance with hospital policy. The findings include:
   a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual hallucinations and with a sitter (1:1) assigned to continuously monitor the patient. Review of the medical record during the period of 12/17/08 at 12:21 AM through 12/18/08 at 1:45 PM identified that Patient #1 was chemically restrained with medication (Ativan and Haldol) and physically restrained with a vest restraint and 4 point soft restraints that progressed to a vest restraint and 4 point leather restraints secondary to elopement attempts, and aggressive and agitated behaviors. Review of the medical record during the period of 12/17/08 at 12:21 AM through 12/18/08 at 1:45 PM failed to identify that restraint orders were renewed every four (4) hours for adults in accordance with the hospital's Restraint policy.

6. Based on review of the medical record and interview with hospital personnel, the hospital failed to ensure that the restraint for one patient (Patient #1) was discontinued at the earliest possible time. The findings include:
   a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual hallucinations and with a sitter (1:1) assigned to continuously monitor the patient. On 12/17/08 at 12:21AM, Patient #1 was physically held by security after attempting to flee the hospital room and was placed in soft bilateral wrist and ankle restraints. Review of the clinical record dated 12/17/08 at 8:00 AM identified that the patient was calm and cooperative, from 10:00 AM through 12:00 PM that the patient was observed to be sleeping, and from 2:00 PM through 8:00 PM, that the patient was in good behavioral control. Documentation failed to support the rationale why Patient #1 continued to be restrained when he/she was observed to be calm, cooperative and/or sleeping. Review of the clinical

EXHIBIT A

DATES OF VISITS: Commencing on December 22, 2008 and concluding on April 1, 2009.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

record on 12/18/08 during the period of 12:22 AM through 5:27 AM identified that when Patient #1's behavior escalated, a vest restraint and four-point leather restraints was applied. Review of the clinical record dated 12/18/08 from 8:00 AM through 10:00 AM reflected that Patient #1's behavior was calm and cooperative and/or that he/she was sleeping. During this time frame a vest restraint and 4-point leather restraints remained in place. During interview on 12/30/08, RN #1 stated that although Patient #1's behavior was calm and cooperative, based on the patient's past history of agitated and aggressive behavior, he/she was reluctant to remove any of the restraints. Review of the hospital's restraint policy identified that patients are released from restraints as soon as the circumstances that warranted their application no longer exist.

7. Based on review of the medical record, review of hospital policy, and interview with hospital personnel, the hospital failed to ensure that one patient, (Patient #1), was monitored every fifteen (15) minutes while in restraints in accordance with the hospital's policy. The findings include:
   a. Review of Patient #1's medical record identified that beginning on 12/17/08 at 12:21 AM through 12/18/08 at 1:45 PM, he/she was restrained with a vest restraint and 4-point soft restraints that progressed to a vest restraint and 4-point leather restraints. Review of the clinical record lacked documentation that the patient was monitored every fifteen (15) minutes. The hospital's restraint policy identified that a patient in restraints for behavioral issues would be monitored every 15 (fifteen) minutes.

8. * Based on observation of Patient #2, review of hospital policy and interview with hospital personnel, the hospital failed to ensure that physicians, inclusive of hospital Residents, received training in the application of restraints according to the hospital policy. The findings include:
   a. Surveyor observation on 12/30/08 identified that Patient #2 was orally intubated, turned to his/her right side and with his/her right wrist restraint tied to the bedrail. During interview on 12/30/08, the Clinical Educator stated that he/she had spoken to the RN caring for the patient who identified that the Resident (physician) had tied the restraint to the bedrail. Review of the facility policy for Use of Restraint and/or Seclusion directed that restraints should never be fastened to the siderail. The policy further identified that education and training must be demonstrated with a documented competency for all medical staff and Residents. During interview on 1/20/08, the Manager of Regulatory Affairs stated that although physicians received a packet of information during general hospital orientation and/or credentialing, no formal program existed for the education of physicians in the ordering and/or use of restraints.

9. Based on review of the medical record and review of hospital policy, the hospital failed to ensure that one patient, Patient #1, was assessed within one hour following initiation of a vest restraint and application of four-point soft and/or leather restraints. The findings include:
   a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

hallucinations and with a sitter (1:1) assigned to continuously monitor the patient. On 12/17/08 at 12:21AM, Patient #1 attempted to elope from the hospital room, was physically held by security and placed in soft bilateral wrist and ankle restraints in accordance with a physician's order. Review of the medical record identified that although during the period of 12/17/08 at 12:21 AM through 12/18/08 at 1:45 PM, a vest restraint and 4-point leather restraints were applied when the patient exhibited threatening, thrashing and combative behaviors, the hospital failed to ensure that a 1-hour face to face evaluation was conducted. The record lacked evidence that a physician's progress note was written within one (1) hour of the initiation of restraint evaluating the patient's immediate situation, reaction to the application of restraints, the patient's medical and behavioral condition and the need to continue or discontinue the restraint. Review of the hospital's Restraint policy identified that in an emergency, the RN may apply restraints; however, the physician must evaluate the patient within 1 hour of initiation of restraints.

10. Based on review of the medical record, review of hospital policy, the hospital failed to ensure that one patient's (Patient #1) behavior, inclusive of the patient's mental status and physical activity, was documented to accurately reflect the need for continued restraint. The findings include:
    a. Review of Patient #1's medical record for the period of 12/17/08 at 12:21 AM through 12/18/08 at 1:45 PM, identified that Patient #1 was placed in four-point soft and/or leather restraints and a vest restraint. Review of the medical record failed to reflect that Patient #1's physical and mental status was assessed to warrant the continued use of the restraints. Although a behavioral assessment was electronically documented when restraints were originally applied, the current mental status displayed during each respective restraint assessment was repeatedly identified as "awake" and/or "sleeping". Physical behavior was repeatedly identified as "scratching" and failed to demonstrate the continued need for mechanical and/or chemical restraint. Review of the hospital's Restraint policy failed to direct staff to monitor the patient's mental status and physical behavior that warranted the continued use of restraint and/or seclusion.

11. * Based on a review of the medical record, review of hospital policies, review of hospital documentation and staff interviews, the hospital failed to ensure the safety of one patient (Patient #1) who required restraints. The finding includes:
    a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes including bizarre thoughts, suicidal ideation and auditory and visual hallucinations with a sitter (1:1) assigned to continuously monitor the patient. Review of the clinical record identified that on 12/17/08 at 12:21 AM, Patient #1 was placed in a vest restraint and four-point soft leather restraints after attempting to elope from the hospital room. On 12/18/08 at approximately 12:30 AM, Patient #1 removed both wrist restraints in the presence of a 1:1 sitter with a vest restraint and four-point soft restraints reapplied. At approximately 5 AM on 12/18/08, in the presence of a 1:1 sitter, Patient #1 removed all restraints and got out of bed. The patient's behavior was so out of control that 9 (nine) staff

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members including multiple security staff were required to apply four-point leather restraints and a vest restraint for the patient's safety. At approximately 1:10 PM on 12/18/08, Patient #1, in the presence of a 1:1 sitter, the patient removed all four-point leather restraints. During interview on 12/30/08, Sitter #2 stated that Patient #1, despite wearing the vest restraint, sat upright in bed, bent at the waist and used his/her teeth to untie one wrist then ultimately, untied his/her other wrist and ankle restraints. During interview on 12/30/08, RN #1 observed that the ties to the vest restraint stretched as the patient leaned forward. Review of the Manufacturer's directions for use of the vest restraint identified that the vest was contraindicated for combative patients. RN #1 failed to ensure that the vest restraint was appropriate to ensure Patient #1's safety. Patient #1 was subsequently restrained with a vest restraint and four-point leather restraints. At approximately 1:45 PM on 12/18/08, Patient #1 removed all restraints for a fourth time in the same manner as described previously. Sitter #1 stated during interview on 12/23/08 that Patient #1 slid down in bed and took off the leather restraint of one wrist with his/her teeth then removed all restraints, including the vest, which was attached to the bed frame at the edge of the mattress with a quick release knot. Patient #1 subsequently jumped through a closed third story window. The hospital failed to ensure that restraints were applied and/or reapplied and/or appropriate to ensure the patient's safety.

12. * Based on observation, review of hospital policy, review of documentation and interview with hospital personnel, the hospital failed to ensure that staff received education and/or training for the appropriate use and application of a vest restraint and/or that the training was reflective for securing a wrist restraint for two (2) of six (6) patients reviewed that utilized restraints (Patient #1 and Patient #2). The findings include:
    a. Review of medical record documentation for restraint monitoring during the period of 12/17/08 through 12/18/08 identified that Patient #1 was consistently identified as wearing a vest restraint for behaviors that included thrashing, hitting and combativeness. The medical record failed to contain orders for the use of a vest restraint. Review of the manufacturer's directions identified that the vest restraint was contraindicated for combative patients. Review of the facility policy for the Use of Restraint and/or Seclusion failed to identify hospital approved restraints. During interview with the Director of Staff Education on 12/30/08, he/she identified that the hospital did not have a policy for application of the vest and that the education department did not educate any staff members in the application of the vest and/or how the vest was to be safely secured to the bed frame secondary to the infrequency of use. Review of the hospital documentation for restraints applied within the last 6 (six) months of 2008, identified that the vest was utilized in 11 (eleven) instances throughout the hospital from 6/1/08 through 12/30/08.
    b. Patient #2 was observed on 12/30/08 with a right wrist restraint secured to the siderails. During interview on 12/30/08, the Clinical Educator identified that a Resident physician had improperly secured the restraint. During interview on 1/20/09, the Manager of Regulatory Affairs stated that although physicians received a packet of information during general hospital orientation and/or credentialing, no formal program existed for the education of

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physicians in the ordering and/or use of restraints.
Review of the hospital's restraint policy reflected that education and training must include demonstrated and documented competency including all medical staff, residents, RN's, security staff, and all staff who have direct patient contact. The training would include initial and on-going education and training in the proper and safe use of restraint application and techniques.
On 12/31/08, the Hospital submitted an action plan to the Department that identified Nursing Leadership (Managers, Supervisors and Charge Nurses) would ensure compliance with the hospital ' s restraint policy inclusive of monitoring restraint use, review of restraint orders and documentation of patient assessment prior to application of restraints as well as ongoing while the patient remained in restraints. All shift Nursing Supervisors, twice daily, were to check the patient, review restraint documentation and conduct one to one education of all staff when compliance issues were identified. Additionally, the facility reviewed the restraint policy with Residents and Hospitalists on 12/22/08 and 12/31/08.

13. * Based on review of hospital documentation, review of quality reports and interview with hospital personnel, the hospital failed to measure, analyze and track quality indicators relative to the utilization of restraints given knowledge that restraint use was a problem-prone area. The findings include:
    a. During interview on 1/6/08, the Chief of Quality and Safety stated that the Department of Nursing identified problems on nursing units with patient restraints one and a half (1.5) years prior. Review of a violation letter dated November 13, 2008, identified that the Hospital had been cited during a State visit in August 2008 for an Emergency Department patient escaping repeatedly from 4 point restraints. The Chief of Quality and Safety stated that during Spring 2008 through the present, patient restraint auditing was stopped so that the hospital could focus on revising the entire restraint program. The Chief of Quality stated that auditing of physician restraint orders was suspended as well and that the hospital never audited the application of restraints as a performance indicator. The Chief of Quality and Safety stated that the Department of Education was responsible for educating staff upon orientation with an annual restraint competency. Review of Patient #1's medical record dated 12/18/08 during the period of 12 AM through 2:00 PM, identified that although Patient #1 had a 1:1 sitter, the patient escaped from 4-point soft and/or leather restraints and a vest restraint four times, and subsequently jumped through a third floor glass window. The hospital failed to focus on quality indicators related to restraint use to prevent patient injury.

14. * Based on review of medical records, review of hospital policy and procedures, and staff interviews, the hospital failed to coordinate services to ensure one patient (Patient #1) received quality medical care when the patient expressed suicidal ideation and/or exhibited psychotic behavior and escaped multiple times from physical restraints and for one (1) of four (4) patients observed (Patient #2) that a wrist restraint was properly applied in accordance with hospital policy.
    a. Patient #1 was seen in the Emergency Department (ED) of the hospital on 12/13/08 and

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12/14/08 for eruption of an itchy body rash and hives over most of his/her body. Patient #1 gave a history of taking Antabuse for the previous twenty (20) days that was provided by a friend and not under the surveillance of a physician. On 12/13/08, Patient #1 was told to stop the ingestion of Antabuse, given Benadryl 50 mg and told to continue the antihistamine at home. The physician narrative dated 12/13/08 identified that the Antabuse was not considered the source of the allergic reaction since the patient had been taking the drug for "close to a month without any difficulty". On the evening of 12/14/08, Patient #1 returned to the ED and was admitted for inpatient stabilization secondary to tachycardia and possible Antibuse reaction and/or alcohol withdrawal. On 12/15/08 at 2 PM, Patient #1 was discharged on the antihistamine, Zyrtec 10mg daily. On 12/16/08 at 7:33 AM, Patient #1 was brought to the ED with mental status changes that included bizarre thoughts, suicidal ideation and auditory and visual hallucinations. On 12/16/08, a Psychiatric Physician's Assistant (PA #1) evaluated Patient #1 on consultation at the request on the Medical Service, however, could not complete a Suicide Risk Assessment secondary to "the patient being unable to have a reality based conversation". Patient #1 was admitted to the hospitals medical unit with the diagnosis of altered mental status with a plan to transfer the patient to Inpatient Psychiatry once deemed medically stable. Review of the History and Physical (H&P) dated 12/16/08, identified that Patient #1 required a 1:1 sitter, Ativan as needed for severe agitation and a Psychiatric evaluation. Review of Patient #1's clinical record dated 12/17/08 at 12:21AM, identified that Patient #1 was physically held by security after attempting to flee the hospital room and was placed in soft bilateral wrist and ankle restraints. Although Resident #1 directed the use of four-point soft restraints on 12/17/08 at 12:21 AM, Resident #1 failed to notify Patient #1's Attending physician of the need for restraint use and/or write a progress note regarding an assessment of the patient in accordance with the hospital's Restraint Order Policy. Review of Resident #1's order for restraints identified that four-point restraints were implemented based on medical rationale (interference with medical devices) although the medical record indicated that restraints were implemented based on the patient's behaviors. Patient #1 was monitored and reassessed in accordance with facility policy for medical restraints. Resident #1 failed to coordinate the patient's care with Psychiatry to develop a plan of treatment to address the patient's exhibited behaviors and/or symptoms. During interview on 1/20/09, the Manager of Regulatory Affairs stated that although physicians received a packet of information during general hospital orientation and/or credentialing, no formal program existed for the education of physicians in the ordering and/or use of restraints.

b. Review of Patient #1's clinical record dated 12/17/08, during the period of 2 PM through 11:35 PM, indicated that the patient's restraints were reduced from four (4) points to two (2) point soft restraints. At 12:00 AM on 12/18/08, Patient #1's demeanor escalated to threatening, aggressive and uncooperative behaviors and he/she subsequently removed both wrist restraints. A vest restraint and 4-point soft restraints to his/her bilateral wrists and ankles were re-applied without a physician's order and/or an assessment by the physician. In addition, at approximately 5 AM on 12/18/08, in the presence of a 1:1 sitter, Patient #1 removed all restraints and got out of bed. The patient's behavior was so out of control that 9

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(nine) staff members including multiple security staff were required to apply four-point leather restraints for the patient's safety. Subsequently, Patient #1 was medicated with Haldol 4 mg intramuscularly and Benadryl 50 mg intravenously with a noted sedating effect. The medical record failed to contain physician orders for the four-point leather and vest restraint and/or an assessment by the physician. Although Patient #1 had escalating behavior and required physical and chemical restraints for the patient's safety, the hospital failed to coordinate a plan of care with Psychiatry to manage the patient's symptoms. Review of Patient #1's clinical record dated 12/18/08 at 1:40 PM identified that although Patient #1 had a 1:1 sitter, the patient released the leather wrist restraints with his/her teeth and refused to be re-restrained for his/her safety. During interview on 12/30/08, RN #1 stated that the patient was not chemically restrained at this time because the "thought was to medicate him/her only as needed, only if he/she was aggressive or combative, which he/she was not". Two security officers reapplied the four-point leather restraints at 1:45 PM on 12/18/08, which were re-checked by RN #1, as specified in the hospital policy. Within the next 15 (fifteen) minutes, in the presence of a 1:1 sitter, Patient #1 released all four leather restraints and the vest restraint. Although additional staff were called to assist, the patient slammed his/her body against the window in the room and then proceeded to run down the hospital hallway and threw his/her body through a closed 3rd story window to the concrete surface below sustaining injuries that included subarachnoid hemorrhage, multiple spinal and rib fractures and a pneumothorax. During interview on 12/30/08, Hospitalist #2 stated that he/she had seen Patient #1 at approximately 11 AM on 12/18/08, and had cleared the patient for transfer to the Psychiatric Unit. He/she stated that PA #1 (Psychiatry) evaluated Patient #1 on 12/16/08, 12/17/08 and on 12/18/08 planned to transfer the patient to the Psychiatric Unit once medically cleared. Hospitalist #2 stated that he/she was not informed of the patient's escalating behavior or that the patient had removed his/her restraints. The Chief of Psychiatry stated during interview on 1/6/09, that psychiatry was acting in a consultative mode for Patient #1 who was in a delirium. He/she stated that although Patient #1 was accepted to the Psychiatry Service, Psychiatry would not manage the patient's behaviors until the patient was on the Psychiatry Unit. Review of the Medical Staff Bylaw Rules and Regulations identified that the duration of the consultant's involvement in the care of the patient was determined by the Attending physician however, the Bylaws failed to address the transfer of patients to other services within the hospital and the onset of the coverage to the accepting service.

c. Patient #2 was observed on 12/30/08 with a right wrist restraint secured to the siderails of his/her bed. During interview on 12/30/08, the Clinical Educator identified that a Resident physician had improperly secured the restraint. During interview on 1/20/09, the Manager of Regulatory Affairs stated that although physicians received a packet of information during general hospital orientation and/or credentialing, no formal program existed for the education of physicians in the ordering and/or use of restraints.
On 12/31/08, the Hospital submitted an action plan to the Department that identified Hospitalists and Resident Physicians were educated regarding the hospital's restraint policy on 12/22/08 and 12/31/08. Additionally, a review of the Psychiatric Consultation procedure

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for the management of patients by the Medical Staff was initiated on 12/22/08.

15. * Based on observation, review of medical records, review of hospital staff education packets, job descriptions, hospital policies, and interviews with hospital personnel, the hospital failed to ensure that nursing supervised and/or evaluated the care provided to one patient (Patient #1), who required restraints. The findings include:
    a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual hallucinations and with a sitter (1:1) assigned to continuously monitor the patient. Review of the clinical record identified that on 12/17/08 at 12:21AM, Patient #1 was physically held by security after attempting to flee the hospital room and was placed in a vest restraint and soft bilateral wrist and ankle restraints. Review of the nursing restraint assessment dated 12/17/08 at 12:30 AM identified Patient #1 as agitated, aggressive, hitting and thrashing. Review of the physician's order failed to identify an order for the vest restraint and indicated that the restraints were applied secondary to the patient interfering with medical devices. Review of the Manufacturer's directions identified that the vest restraint was contraindicated for combative patients. Although the vest restraint was implemented without a physician's order and contraindicated for Patient #1, review of the medical record identified that Patient #1 remained in the vest restraint through 1/18/08 at 1:45 PM.
    b. Review of Patient #1's clinical record identified that on 12/17/08 at 12:21 AM, the patient was placed in a vest restraint and four-point soft bilateral wrist and ankle restraints. On 12/18/08 at approximately 12:30 AM, Patient #1 removed both wrist restraints, in the presence of the 1:1 sitter, and that the vest restraint and four-point soft restraints were subsequently reapplied. At approximately 5 AM on 12/18/08, in the presence of the 1:1 sitter, Patient #1 removed the vest and the four-point soft restraints and was noted to be extremely combative. A vest restraint and four-point leather restraints were applied, in addition to the administration of Haldol, Ativan and Benadryl. At approximately 1:10 PM on 12/18/08, Patient #1, in the presence of a 1:1 sitter, removed the vest and 4-point leather restraints. During interview on 12/30/08, Sitter #2 stated that Patient #1, despite wearing the vest restraint, sat upright in bed, bent at the waist and used his/her teeth to untie one wrist then ultimately, untied his/her other wrist and ankle restraints. During interview on 12/30/08 RN #1 identified she has observed that the ties to the vest-restraint stretched as the patient leaned forward. Security was called and the patient was again restrained with a vest restraint and 4-point leather restraint. At approximately 1:45 PM on 12/18/08, Patient #1 removed all restraints (vest and 4-point leathers) for a fourth time in the same manner as described previously. Sitter #1 stated during interview on 12/23/08 that Patient #1 slid down in bed and took off the leather restraint of one wrist with his/her teeth then proceeded to remove the remainder of the restraints (wrist and two ankles), including the vest, which was attached to the bed frame at the edge of the mattress with a quick release knot. Patient #1 was able to escape from restraints on four (4) occasions, despite the presence of the 1:1 sitter, and subsequently jumped through a closed third floor window of the medical unit. The clinical record lacked evidence that Patient #1 was assessed every fifteen (15) minutes

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in accordance with the hospital's restraint policy. Additionally, although review of a nurse's note dated 12/18/08 at 5:27 AM indicated that four-point leather restraints were applied to Patient #1, a physician's order for the use of these restraints failed to be documented.

c. During interview on 12/22/08, the Manager of Risk Management stated that the documentation forms completed by the sitter when Patient #1 required continued monitoring (1:1) from 12/16/08 through 12/18/08, although not part of the medical record, should be maintained on the nursing unit. The hospital was unable to provide to the surveyor documentation that reflected the continuous monitoring of Patient #1. Review of the Hospital's "Sitter Responsibilities" directed hourly monitoring of patient activity and behavior under the direction and supervision of the nurse. Nursing staff failed to ensure that the Sitter staff assigned to care for Patient #1 were able to provide the 1:1 supervision that Patient #1 required.

Interview on 12/30/08 with the Support Assistant (Sitter #2) who relieved Sitter #1 on 12/18/08 at 1:10 PM, identified that he/she had been oriented to the Sitter role. Review of the job description for the Support Assistant failed to identify that that the role included observation of patient activity on a 1:1 basis. Review of the hospital's restraint policy identified that a Behavioral Health Unit Staff member must remain with the restrained patient at all times.

On 12/31/08, the Hospital submitted an action plan to the Department that identified Nursing Leadership (Managers, Supervisors and Charge Nurses) would ensure compliance with the hospital ' s restraint policy inclusive of monitoring restraint use, review of restraint orders and documentation of patient assessment prior to application of restraints as well as ongoing while the patient remained in restraints. All shift Nursing Supervisors, twice daily, were to check the patient, review restraint documentation and conduct one to one education of all staff when compliance issues were identified.

16. Based on review of the medical record, review of hospital policy and interview with hospital personnel, the hospital failed to ensure that Patient #1's Care Plan included specific interventions related to the implementation of chemical and mechanical restraints to ensure safety during altered mental states. The finding includes:

a. Patient #1 was admitted to the hospital's medical unit on 12/16/08 at 5 PM with mental status changes that included bizarre thoughts, suicidal ideation, auditory and visual hallucinations and with a sitter (1:1) assigned to continuously monitor the patient. Review of the Care Plan identified problems of impaired communication; high risk for injury secondary to mental confusion and drug therapy; high risk for violence secondary to acute agitation, suicidal behavior and hallucinations/delusions; and high risk for falls secondary to restraints and medication effects, however, the plan failed to include specific approaches and modifications regarding the use of restraint and/or seclusion coupled with medication use to safely manage the patient's out of control aggression and ability to repeatedly remove himself/herself from physical restraint.. During interview on 12/30/08, RN #1 stated that since the patient was undergoing a suspected adverse drug reaction, "the thought was to medicate him/her only when absolutely necessary (for increased aggression)". Patient #1,

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who had orders for medications including Haldol, Ativan and Benadryl and had twice shown the pattern of quick escalation to aggression and quick escape from restraint (12/18/08 at 12:30 AM and 5 AM), was not medicated from 5 AM on 12/18/08 through 2 PM on 12/18/08, when he/she twice (in quick succession) removed himself/herself from leather restraints and jumped through a closed window.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical record (1) and/or (3) and/or (e) Nursing service (1) and/or (i) General (6).

17. Based on review of the medical record and review of hospital policy, the hospital failed to ensure that RN #2 documented sedative medication given to one patient (Patient #1) during a behavioral outburst. The findings include:
    a. On 12/16/08 at approximately 5 PM, Patient #1 was admitted from the Emergency Department (ED) with mental status changes, including bizarre thoughts, suicidal ideation and auditory and visual hallucinations. The patient was medicated with Ativan for agitation and aggressive behavior while in the ED. A 1:1 sitter was placed with the patient and security was present when the patient was admitted to the medical unit. Review of the physician orders dated 12/17/08 at 12:30 AM identified an order for Ativan 2 mg Intravenously every two (2) hours as needed. On 12/17/08 at 12:21AM, Patient #1 was physically held by security after attempting to flee the hospital room and was placed in a vest restraint and soft bilateral wrist and ankle restraints. Review of the nursing narrative dated 12/17/08 at 1:02 AM identified that Patient #1 was given Ativan 2 mg intravenously and placed in a restraint vest and four-point soft restraints. Review of the EMAR, (Electronic Medication Administration Record) for 12/17/08 from 12 AM through 7 AM failed to reflect that Ativan 2 mg was administered.

18. Based on review of the certified medical record for Patient #1, the hospital failed to provide a complete and accurate printed medical record reflective of all aspects of the electronic medical record as reviewed by the Surveyor at the hospital. The findings include:
    a. Review of Patient #1's printed medical record, which had been certified by the Hospital as complete, failed to reflect that physician orders for the medications Benadryl, Ativan and Haldol. Review of nursing narrative notes during the period of 12/16/08 through 12/18/08 indicated that these medications were administered.
    b. Review of Patient #1's printed certified record failed to include the Electronic Medication Administration Record (EMAR) that identified medications administered during the patients hospitalization from 12/16/08 at 5 PM through 12/18/08 at 2 PM.
    c. Review of Patient #1's Care Plan failed to be included in its' entirety, inclusive of identified problems and active interventions.
    d. Patient #1's certified record failed to include documentation of restraint assessment inclusive of type of restraint applied, time restraint applied, reason/rationale for the restraint, alternatives attempted, behaviors elicited by the patient and patient assessment while

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restrained.

e. Review of Patient #1's medical record identified that the electronic documentation of restraint monitoring failed to reflect the same level of restraint application as documented in the nurse's note. Review of the Nurse's narrative dated 12/17/08 at 9 PM, identified that bilateral wrist restraints were removed, however, electronic documentation identified that from 12/17/08 at 2 PM until 12/17/08 at 11:25 PM, the patient remained in bilateral wrist restraints, with posy vest and bilateral leg restraints off. Additionally, medical record documentation, either written or electronic, failed to show the specific time that restraints were released, changed and/or discontinued.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (3) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6) and/or (l) Infection control (1)(A).

19. * The facility failed to ensure that the contracted dialysis service provided Bacterial entotoxin level testing in accordance with the applicable dialysis conditions of participation and standards as per ANSI/AAMI RD 52:2004 7.2.4. Bacterial endotoxin testing. The findings are based on review of facility documentation and staff interview and includes the following:
    a. Review of the acute hemodialysis water monitoring documentation indicated that although monthly water cultures had been obtained and monitored, the facilities contracted dialysis service failed to monitor the endotoxin levels in the water utilized for hemodialysis. Interview with the Dialysis Nurse on 3/23/09 at approximately 11:00 AM, identified that endotoxin levels were not monitored and that this had been the decision of the Medical Director of the hemodialysis program because the facility utilizes "low flux" dialyzers. Documentation failed to be provided to the surveyor regarding the rationale, that by utilizing low flux dialyzers, endotoxin levels do not need to be monitored.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2)(B) and/or (4)(A) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (g) Pharmacy (1) and/or (i) General (6).

20. Based on review of the clinical record, interview and review of facility policy, the facility failed to ensure that the attending was notified by the physician of Patient #35 who was identified as hitting his/her head on 6/25/08 after experiencing a fall and subsequently required a craniotomy on 6/27/08. The findings include the following:
    a. Review of Patient #35's clinical record indicated that the patient was admitted on 6/23/08 for an angioplasty of the left lower extremity. The patient had a history of peripheral vascular disease and atrial fibrilation and was on Coumadin. Review of the clinical record indicated that on admission, the patient had been on Coumadin. On 6/23/08, a PT of 16.6 (normal 9.0-11.6) and a PTT of 34.3 (normal 23-33) was identified. The patient's Coumadin was stopped and the patient had been ordered to receive Lovenox 60 mg twice a day.

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Documentation identified that Patient #35 had received two doses of Levonox as ordered on 6/25/08. Review of the nurses note dated 6/25/08 indicated that at 1:10 AM, the patient was out of bed in the wheelchair, the wheelchair fell backwards with the patient hitting his/her head on the floor sustaining a quarter sized contusion. Review of the physician's note dated 6/25/08 indicated that MD #7 was called to see Patient #35 due to a fall. The note indicated that the patient had fallen out of a wheelchair and per the RN, the patient had hit his head. The note indicated that the Patient's head was non-tender, that there was minimal swelling to the right occipital area and that the patients mental status was unchanged. The physician's note failed to identify that an attending physician had been consulted and/or notified. Interview with Risk Management Staff #1 identified that MD #7 had finished his/her residency and no longer worked at the hospital. Interview further identified that when the case had been reviewed by the facility, MD #8, the patient's attending physician, indicated that he/she did not recall being notified that the patient had fallen on 6/25/08. Review of the facility policy related to falls indicated that if a patient fell on an off shift, the patient would be evaluated by the physician on duty and that he/she would notify the attending physician. The clinical record indicated that on 6/26/08, the patient experienced a change of condition and on 6/27/08, the patient had a large right subdural hematoma requiring a craniotomy.

21. * Based on review of the clinical record, interview and review of facility policies and procedures for one (1) patient who required intravenous pain medication (Patient #60), the facility failed to ensure that the order for Fentanyl was complete. The findings include:
    a. Patient #60 arrived at the Hospital Emergency Department on 2/25/09 at 6:20 AM with complaints of abdominal pain, was diagnosed with pancreatitis and was admitted to the hospital. Review of the clinical record reflected that Patient #60 was transferred to the Critical Care Unit (CCU) on 2/27/09 for management of tachycardia, hypotension and sedation. Review of the physician orders dated 2/28/09 at 6:15 AM directed the staff to administer an opioid analgesic (Fentanyl) intravenously via continuous infusion and to titrate the dose according to the "desired pain scale". The clinical record reflected that the Fentanyl infusion was initiated on 2/28/09 at 8:00 AM at a rate of 25 micrograms per hour (Mcg/Hr). The nursing assessment identified that Patient #60 expressed nonverbal signs of pain. On 2/28/09 at 9:00 AM the Fentanyl dose was increased to 50 Mcg/Hr, at 12:00 Noon the dose was increased to 100 Mcg/Hr, at 3:00 PM the dose was decreased to 80 Mcg/Hr and at 11:00 PM the dose was increased to 90 Mcg/Hr. Documentation did not indicate that the patient's level of pain was assessed with the dose changes. On 3/1/09 at 2:00 AM the Fentanyl dose was increased to 180 Mcg/Hr and at 3:00 AM the dose was increased to 200 Mcg/Hr. Documentation did not indicate that the patient's level of pain was assessed with the dose changes. The record reflected that on 3/3/09 at 10:00 AM the Fentanyl dose was increased to 300 Mcg/Hr, on 3/5/09 at 12:00 Noon the dose was increased to 500 Mcg/Hr, at 1:00 PM the dose was increased to 540 Mcg/Hr and at 2:00 PM the dose was again increased to 600 Mcg/Hr. The physicians order failed to identify a maximum dose for the medication. Interview and review of Patient #60's clinical record on 3/17/09 with RN #6, identified that there was no consistent assessment of the patient's level of pain with regards

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to the increases and/or decreases of the Fentanyl doses. Interview with the Manager of Regulatory Affairs on 4/13/09, identified that according to the Hospital pharmacy department, the maximum dose for this patient would have been 800 micrograms per hour and that the maximum dose was never administered. Review of the Hospital documentation, titled " ICU Physician's Pain Orders ", identified that for Fentanyl the titration pain goal must be identified (using a pain scale of 0 to 10 where 0=no pain and 10=worst pain).

22. * Based on review of clinical records, review of facility policies, observations and interviews, the facility failed to ensure that preventive measures and/or monitoring of pressure ulcers were consistently implemented as per facility policy for two (2) of four (4) patients reviewed, Patients #46 and 60. The findings include:
    a. Patient #46 was admitted to the facility on 3/13/09 with diagnoses that included Parkinson's and dementia. Review of the nursing assessment dated 3/13/09 identified that Patient #46 entered the facility with a Stage II pressure ulcer on the left buttocks that measured 5.0 by 3.0 cm. and was pink and red. On 3/16/09, the documentation identified that Patient #46's left buttock's wound was now 5.50 cm. by 1.0 cm. with yellow slough, that the patient had developed a second Stage II pressure ulcer on the right buttock that measured 4.0 by 2.0 cm., and that Mepilex dressings were applied to both areas. A wound consult dated 3/17/09 directed the continued application of Mepilex dressings to the ulcers. Observation on 3/18/09 at 10:45 AM identified that Patient #46's wounds were uncovered. Interview with RN #1 at the time of the observation identified that the wounds were uncovered upon his/her arrival at the start of the shift and that he/she believed the areas were to be left open to air. Subsequent to surveyor inquiry, Mepilex dressings were applied in accordance with the Wound Consultant's recommendations.
    Interview with facility staff on 3/18/09 at 10:00 AM identified that Patient #46 had been sitting in the bedside chair since approximately 8:30 AM and was observed to be without the benefit of a pressure reducing/pressure relieving chair cushion. Observation of Patient #46's transfer back to bed at 10:30 AM identified that the patient had been sitting on multiple layers of folded bath blankets. Interview with the charge nurse at the time of the observation identified that the unit had limited storage for chair cushions and that if needed, the staff would need to search for a cushion from another patient's room. Upon surveyor inquiry, a pressure relieving chair cushion was obtained for Patient #46's chair from another patient's room. Upon observation of Patient #46's left buttocks pressure ulcer at 10:45 AM, the ulcer was observed to have an approximate 2.5 cm. deep purple center with a folded skin flap at the center of the purple area.
    b. Patient #60 arrived at the Hospital Emergency Department on 2/25/09 at 6:20 AM with complaints of abdominal pain, was diagnosed with pancreatitis and was admitted to the hospital. Review of Patient #60's clinical record reflected that on 2/25/09, the patient's skin was intact. On 3/10/09 at 8:00 AM, the clinical record identified that Patient #60 had a skin tear on his/her left cheek. Documentation failed to indicate the size of the area as per facility policy. On 3/14/09 at 6:50 AM, the record reflected that Patient #60 had pressure sores on

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both heels. Documentation failed to indicate the size and/or the condition of the skin and/or surrounding tissue. Observation of Patient #60 on 3/16/09 with RN #7, identified that the left heel skin was black in color, had no drainage, measured 3.5 to 4.0 centimeters (cm) long by 4.25 cm wide and was intact. The right heel skin was observed to be black in color, had no drainage, had areas that measured 1.5 long by 1.0 cm wide and 1.0 cm long by 1.0 cm wide and was intact. Interview with RN #6 on 3/16/09, identified that alterations in skin integrity are only measured if the skin is not intact and that there are no measurements for Patient #60's heels.

Review of the facility's Pressure Ulcer Prevention Protocol directed that pressure ulcers were to be assessed initially and thereafter with any significant changes in the wound, after procedures such as debridement, or dressing changes. The policy directed that the assessment would include the exact location of the wound, stage, measurements that included length, width, and depth, characteristics of the wound bed, condition of surrounding tissue, drainage, odor, pain level and dressing type used. The policy identified that for any skin alteration; a complete description must be documented. In addition, the policy directed that chair cushions be used as appropriate and to limit sitting time to frequent shorter periods rather than one long period.

23. Based on review of the clinical record, review of facility policy, and interview, the facility failed to ensure that the plan of care was consistently implemented for one (1) of two (2) patients reviewed, Patient #15, who required daily weights. The findings include:
    a. Patient #15 was admitted to the facility on 3/9/09 with diagnoses that included severe anemia and a history of dementia. Review of the nursing care plan dated 3/9/09 identified a potential for fluid volume deficit with interventions that included monitoring the patient's intake and output at least every eight hours and to obtain daily weights. Review of the clinical record identified that Patient #15's weight was not obtained on 3/14/09, 3/15/09 and 3/16/09. Interview with facility staff identified that the facility had built in bedscales to assist staff in obtaining required weights and that they were unsure as to why Patient 15's weight had not been obtained in accordance with the plan of care.

24. Based on review of the clinical record, interview and review of facility policy, the facility failed to ensure for the one patient reviewed who had experienced a fall (Patient #35) that the patient was assessed following the fall. The findings include the following:
    a. Review of Patient #35's clinical record indicated that the patient was admitted on 6/23/08 for an angioplasty of the left lower extremity. The patient had a history of peripheral vascular disease and atrial fibrilation and was on Coumadin. Review of the clinical record indicated that on admission, the patient had been on Coumadin. On 6/23/08, a PT of 16.6 (normal 9.0-11.6) and a PTTof 34.3 (normal 23-33) was identified. The patient's Coumadin was stopped and the patient had been ordered to receive Lovenox 60 mg twice a day. Documentation identified that Patient #35 had received two doses of Levonox as ordered on 6/25/08. Review of the Nurses note dated 6/25/08 indicated that at 1:10 AM, the patient was out of bed in the wheelchair and fell backwards hitting his/her head on the floor

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sustaining a quarter sized contusion. The note further indicated that the patient's vital signs were stable and that the patient was alert and oriented times three. The nurse's note dated 6/25/08 at 6:00 AM indicated that the patient complained of dizziness and was instructed to go back to bed. Vital signs were stable, a blood sugar was done which was 94, the patient was offered juice and settled in bed. Review of the clinical record failed to identify that the patient's neurological status had been assessed after the fall or when the patient complained of dizziness. Interview with RN #9 indicated that after Patient #35 fell, a neurological assessment had not been completed. RN #9 indicated that the patient was alert and that MD #7 had seen the patient and had no additional orders and/or restrictions. Review of the facility policy related to falls indicated that if a patient falls and reports hitting their head, a neurological assessment should be performed. The policy failed to identify when and how often the assessment should be completed. The patient was subsequently identified on 6/27/08 to have a large right subdural hematoma requiring a craniotomy.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical record (3) and/or (e) Nursing service (1) and/or (i) General (6).

25. Based on review of the clinical record, interviews and review of facility policy and procedures for one patient (Patient #62) that was identified at risk for falls, the facility failed to ensure a physical therapy referral was obtained as per the patient's plan of care. The findings include:
    a. Patient #62 arrived at the Emergency Department (ED) on 3/15/09 at 6:14 P.M., from a rehabilitation facility, with an alteration in his/her mental status and low oxygen saturation. The patient was diagnosed with congestive heart failure and admitted to the Hospital. Review of the clinical record identified that Patient #62 was at risk for a fall and the interdisciplinary plan of care dated 3/16/09, included the intervention to complete a physical therapy referral. Interviews with RN #4 and RN #5 on 3/17/09, identified that a physical therapy referral had not been initiated.

26. Based on review of the clinical records, interviews and review of facility policy, the facility failed to ensure that comprehensive, individualized care plans had been completed for two (2) of two (2) clinical records reviewed for patients with behavioral health issues (Patients #16 and #20). The findings include the following:
    a. Review of Patient #16's clinical record indicated that the patient was admitted on 3/2/09 with bipolar disorder. Review of the interdisciplinary treatment plan (ITP) dated 3/3/09 and updated on 3/9/09, failed to identify interventions to be implemented to achieve the identified desired outcomes. Interventions identified were to assess thought process and provide groups and activities. The ITP failed to specifically identify what to assess regarding the patients thought process and which groups and activities the patient should attend to achieve the desired outcomes.
    b. Review of Patient #20's clinical record indicated that the patient was admitted on 2/27/09 with delusional disorder. Review of the clinical record indicated that on 3/3/09, the patient

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was seen by the hospitalist and diagnosed with a urinary track infection and hypertension. The patient was started on an antibiotic and an antihypertensive on 3/3/09. Review of the interdisciplinary treatment plan (ITP) dated 3/2/09 and updated on 3/9/09 failed to address the medical problems.

Interview with the Charge Nurse on 3/18/09 indicated that they were in the process of revising the ITP's to address the groups and specific interventions. Review of the facility policy indicated that an ITP would be completed with the input of the team and that it would be comprehensive.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2)(B) and/or (d) Medical record (3) and/or (7) and/or (e) Nursing service (1).

27. Based on review of the medical records, review of facility policy, review of Medical Staff Bylaws and interviews with facility personnel, for three (3) of ten (10) medical records reviewed for invasive procedures, the facility failed to ensure that the medical record was dated, timed and/or complete. The findings include:
    a. Patient #25 underwent a left cardiac catheterization on 3/10/09. Review of the medical record identified two Invasive Procedure Reports dated 3/10/09, although reflecting the same procedure, documented that the procedure occurred in different rooms and with different staff, rendering it impossible to define the correct procedure report. Interview on 3/18/09 at 2:45 PM with the Charge Nurse and the Manager of the Cardiac Cath Lab identified that following the completion of the cardiac catheterization of Patient #25, it was determined that additional information needed to be added to the report. Due to the nature of the electronic documentation program utilized, the information could not be added during the procedure. The Manager stated that the Procedure Report was then added to the medical record during Patient #25's recovery without removing the original report. Additionally, the report failed to include the names and times of attendance that relief staff provided during the procedure. Interview with the Manager of Regulatory Affairs on 3/30/09 at 1:00 pm identified that the hospital lacked a policy governing utilization and/or documentation of use of relief staff during a procedure.
    b. Patient #27 underwent a fistulogram on 3/6/09. Review of the medical record failed to identify an immediate post procedure note. The dictated procedure note was dated 3/9/09 and was signed as approved on 3/17/09. Review of the Medical Staff Bylaw Rules and Regulations identified that a procedure report should be dictated immediately after the procedure completion and a written post-procedure note should be documented in the medical record.
    c. Patient #28 underwent a right knee menisectomy on 3/16/09. Review of the medical record failed to identify that a post-operative note had been written. Review of the Medical Staff Bylaw Rules and Regulations identified that a Post-operative note should be written immediately after the surgery.

28. Based on review of the clinical record, review of facility policies and Medical Staff Bylaws and

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interview, the facility failed to ensure that a discharge summary was completed for one (1) patient reviewed (Patient #37), who was admitted to the hospital following a cardiac/respiratory event post a uterine embolization procedure. The findings include:

a. Patient #37 was admitted to the facility on 9/17/08 for the purpose of undergoing a uterine embolization due to a recurrence of endometrial cancer. The clinical record identified that Patient #37's medical history included renal failure that required regular hemodialysis treatments, a history of Myocardial Infarctions (heart attacks), previous cardiac arrests, severe vascular disease, and Atrial Fibrillation (A-Fib). Documentation further identified that the patient's A-Fib was being treated with Coumadin prior to 9/17/08 but that the Coumadin had not been taken since 9/12/08 in preparation for the embolization. Interview with RN #3, the Angio Nurse Specialist, on 3/20/09 at 10:40 AM identified that Patient #37 was at baseline A-Fib throughout the entire procedure with a heart rate in the 80's to 90's and that his/her blood pressure remained stable. Upon return to the holding area, RN #3 stated that Patient #37 became very anxious and that he/she was unable to get the patient's right foot pulses utilizing a Doppler. Patient #37 became increasingly anxious, diaphoretic, and tachypneic, and the Rapid Response Team (RRT) was called at 12:25 PM. During the RRT assessment, Patient #37 became unresponsive and was subsequently intubated to ensure airway protection during the event and subsequently transferred to the Critical Care Unit (CCU). Physician progress notes dated 9/18/08 and 9/19/08 identified that Patient #37 had experienced liver and spleen injury likely due to ischemia. On 9/18/08, Patient #37's respiratory status improved and that patient was extubated. Patient #37 requested that his/her status be made a "Do Not Resuscitate/Do Not Intubate" and insisted that he/she be discharged to home as soon as possible. Patient #37 was discharge on 9/19/08 to home at her request under Person #1's care and with Hospice services. Although Patient #37 was evaluated by multiple specialty physicians including pulmonary, oncology, cardiology, radiology and hospitalists, as well as CCU residents/interns during the hospital course from 9/17/08 through 9/19/08, no discharge summary was dictated upon her discharge and/or within the thirty days following Patient #37's discharge. Interview with facility staff identified that multiple attempts to locate a discharge summary were unsuccessful. Medical Staff By-Laws identified that a discharge summary was not necessary for an inpatient stay of less than forty eight hours in most circumstances, however facility policy directed that a discharge summary must be completed for any CCU stay or any two day stay in which there is a complication with care.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (a) Physical plant (4) and/or (b) Administration (2) and/or (c) Medical staff (4)(A) and/or (e) Nursing service (1) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (2) and/or (6) and/or (l) Infection control (1)(A).

29. * Based on observation, review of facility documentation and staff interviews, the facility failed to ensure that the Tully Center OR's were maintained. The findings are as follows:

a. A tour of the Tully Outpatient Surgical Center on 3/19/09 at approximately 10:15 AM with

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the Director of Engineering identified that throughout Operating Rooms #1 through 6, floors were found to be ripped and torn at the seams and walls throughout the rooms were either damaged (e.g. exposed sheetrock, exposed metal cornerbead and/or chipped paint, and/or had exposed joint compound) rendering the surfaces unable to be properly cleaned.

b. Operating Rooms #1 through 6 were observed with rusty casters on equipment that included IV poles, metal carts and/or metal kick buckets.

c. Throughout the corridors of the OR suite, walls were observed damaged and/or partially repaired with unfinished paint/compound.

d. The facility was lacking proper and/or inaccurate signage throughout the OR suite e.g. although the sign identified equipment storage, trash was observed in the room, although the sign identified soiled utility, it contained clean supplies.
Interview with the Director of Tully Center Maintenance on 3/19/09 identified that although he/she routinely tours and does whatever maintenance he/she can, the operating room staff needs to put in work orders for larger projects which they are not doing. Interview further identified that the maintenance staff at Tully work day ends at the same time as the surgical staffs.
Interview with the Operating Room Manager of the Surgical Center on 3/19/09 identified that the operating rooms are utilized throughout the day, limiting maintenances access to the ORs during operating hours.
During interview on 3/30/09, the Infection Control Nurse stated that he/she does quarterly rounds in the ORs, that they remain flexible to where the need is, and that he/she could not recall the last time a tour was completed of the OR's at the Tully Surgical Center by Infection Control Practitioners. Interview further identified that when they tour areas they often go as a group and when issues are identified they would be communicated to the Manager of the OR.
Review of the document, Environment Rounds 2008, submitted by the facility on April 1, 2009 identified that that on 10/1/2008 in the Operating Rooms at the Tully OR location, that issues of floor and walls needing repair were identified with the responsible party as Engineering to address the issues. The area for the date resolved was blank. Documentation further identified that the rounds were conducted by the Assistant Director of Engineering/Facilities and the Director of Safety and Security, and that the Director of Engineering/Facilities was notified of the rounds. No work order was identified as generated.
Work orders pertaining to Tully OR repairs were requested and the facility provided a work report that identified on 2/19/09 work was requested by Tully Maintenance to "check all sterile halls and rooms caulk any crack in flooring". Work was identified as done on 2/20/09, 2/23/09, 2/27/09 and 3/4/09 for a total of nine (9) hours spent on the request and the work was identified as completed on 3/4/09.

30. * Based on observation, review of the sterrad biological testing log, review of facility policy and interview with facility personnel, the facility failed to ensure that the Sterrad biological testing documentation reflected accurate incubator dwell times as per facility policy. The findings

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include:

a. During a tour of the Central Sterile Department in the hospital on 3/16/09 and the Central Sterile Department of the Surgical Center on 3/19/09, it was identified that for the four (4) Sterrad machines, biological testing documentation failed to have timed entries for insertion and removal of the testing vial from the incubator to ensure accurate test results. Review of the documentation for the month of March 2009 identified that Central Sterile staff members initialed the placement in and the removal of the vial from the incubator. During interview on 3/16/09, the Supervisor of the Central Sterile Department identified that the incubation time for test indicators utilized by the hospital was 48 hours. Although review of the facility policy for Biological Monitoring for Sterilization Practices identified that biological indicator test results should be interpreted in the time frame specified by the biological test manufacturer and should be included in all sterilization records, the policy failed to stipulate the actual timeframe.

31. * Based on tour of the Tully Surgical Center on 3/19/09, review of facility policy and interview with facility personnel, the facility failed to ensure that appropriate infection control practices were implemented. The findings include:
    a. During tour of the Tully Surgical Center on 3/19/09 with the Manager of Regulatory Affairs, observation of gel pads and cushions utilized for patients during Stereotactic Breast biopsy were observed to be lying on the floor. Interview with the Manager of the Surgical Center OR on 3/19/09 identified that such items should be stored off the floor. Review of the facility policy for Infection Control -Nursing Care Units, identified that unit personnel were responsible to clean items utilized by patients.
    b. During tour of the semi-restricted outer hallway of the OR, a room labeled "soiled holding" was observed to store clean supplies that included boxes of clean gloves, clean suction canisters and books. This room was located next to the decontamination room of the central sterile department and was adjacent to the room utilized to store sterile OR packs. OR staff were observed to wheel soiled case carts through the room. During interview on 3/19/09, the Manager of the OR stated that all clean supplies would be removed from this room.
    c. Observation of the room labeled "equipment" identified that multiple biohazard containers and regular trash containers were overflowing. Two biohazard containers were observed to have the lids open secondary to overflow. Interview with the Manager of Regulatory Affairs on 3/30/09 at 1:00 PM identified that the hospital lacked a policy delineating the safe storage of biohazard trash.
    d. Observation of cleaning of the OR between cases on 3/19/09, identified that the OR table was wiped with a cloth that failed to leave a wet mark on the mattress. Review of the manufacturer's directions for the PDI Super Sani-Cloth identified that to disinfect a surface, the surface should remain wet for a total of two minutes and then allowed to air dry. The directions stipulated the addition of multiple wipes to attain the required wetness of the surface to achieve disinfections. Review of the OR cleaning policies identified a failure to delineate the process for disinfections of the OR table.

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32. Based on review of the clinical record and review of facility policy, the facility failed to ensure that the discharge summary for Patient #35 that had been dictated on 7/2/08, nine (9) days prior to the actual discharge on 7/11/08, had been completed as per facility policy for Patient #35. The findings include the following:
    a. Review of Patient #35's clinical record indicated that the patient was admitted on 6/23/08 for an angioplasty of the left lower extremity. The clinical record identified that on 6/25/08, the patient fell hitting his/her head and on 6/27/08, the patient required a craniotomy due to a large right subdural hematoma. Review of the clinical record indicated that although the patient's discharge summary had been dictated on 7/2/08, the patient was not discharged from the facility until 7/11/08. The record failed to contain an addendum and/or updated discharge summary covering the 9 days the patient remained in hospital following the dictated summary of 7/2/08. Further review indicated that the patient discharge plan form had not been completed as per facility policy. Review of the Medical Staff Rules and Regulations indicated that the discharge diagnosis and the patient's condition on discharge must be recorded and that the discharge plan form be completed prior to discharge.

33. Based on observation, staff interview and review of facility policy, the facility failed to ensure that appropriate foot attire was worn by MD #10 during a surgical procedure as per facility policy. The findings include:
    a. During a tour of the facility on 03/17/09 at approximately 11:00AM, the surveyor observed MD#10 ambulating in the Operating Room in the area of the anesthesia machine while surgery was in progress in socks without shoes. MD #10 was observed to sit down in a chair in front of the anesthesia machine and place his/her feet on the base drawer of the machine. Interview with the Charge Nurse of the main OR that was touring with the surveyor during the time of this observation when asked if this was common practice in the OR indicated that this was not and that he/she would have a staff member go into the room to remind MD#10 to put his/her shoes on. Review of the facility policy entitled "Surgical Attire in the Operating Room" included that shoes worn within the surgical environment should be clean and closed toed.

34. Based on review of the medical record, review of facility policy and interview with the Chief of Anesthesia, for one (1) of four (4) anesthesia records reviewed in vascular interventional radiology, the anesthesiologist failed to record the total dose of propofol delivered to Patient #26. The findings include:
    a. Patient #26 underwent a trans intra hepatic portal shunt (TIPS) procedure on 3/11/09. Review of the Anesthesia Record identified that the patient received 75 mcg of Fentanyl and Propofol, however, the dose of the drug failed to be identified on the record. Review of the Anesthesia policies identified that the total dose of the drug administered should be

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documented. During interview on 3/19/09, the Chief of Anesthesia identified that the total dose of the drug should be documented.

35. Based on review of the clinical record and review of Medical Staff Rules and Regulations, the facility failed to ensure for one (1) of seven (7) post anesthesia evaluations reviewed, that Patient #35 had a post anesthesia evaluation as per Medical Staff Rules and Regulations. The findings include the following:
    a. Review of Patient #35's clinical record indicated that on 6/27/08, the patient had a craniotomy as a result of a large right subdural hematoma. Review of the anesthesia record dated 6/27/08 failed to identify that an anesthesia note had been done. Review of the Medical Staff Rules and Regulations indicated that a post anesthesia evaluation of all patients was to be done within forty-eight hours after the procedure.

The following are violations of 19a-36-D35(c) Responsibilities of Director.

Coagulation:

36. Based on surveyor observation, record review, and interview with the Coagulation supervisor, it was determined that the ISI (International Sensitivity Index) value was not correct for the Simplastin Excel lot in use. The findings include:
    a. At the time of inspection on March 17, 2009, a review of Coagulation records indicated that the current lot in use of Simplastin Excel (Lot 111489 –ISI 1.79) was not the same ISI value programmed into the Coagulation Coag A Mate Instrument (ISI 1.71). Further investigation revealed that the old ISI value from the previous lot was 1.71. The supervisor confirmed that the ISI values did not agree.

Microbiology:

37. Based on surveyor inspection of the microbiology refrigerator and interview with laboratory staff, it was determined that the laboratory failed to monitor expiration dates to ensure that supplies were not used beyond their expiration dates. The findings include:
    a. At the time of inspection on March 17, 2009, the following testing materials were observed in the microbiology refrigerator and laboratory staff confirmed they had expired.

Testing Material	Amount	Expiration Date
CM Plates	16	01/02/2009
BCYE		
Selective Agar	4	02/18/2009
Sabouraud Dextrose		
Tubed Media	33	01/15/2009
Lysine Agar		
Tubed Media	31	12/28/2008

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The following are violations of 19a-36-D38. Minimum standards for the operation of clinical laboratories.

38. Based on surveyor observation of the microbiology TB room and confirmed by interview with the laboratory supervisor and laboratory staff, it was determined that adequate safety precautions were not enforced to protect against biological hazards. The findings include:
    a. At the time of inspection on March 17, 2009, the following food items were observed in the TB room while a technician was working at the bench:
    2 Cups of Tea
    1 Cup of Coffee
    3 bottles of Water
    1 can of cookies
    1 box of Girl Scout cookies
    The laboratory supervisor and laboratory staff confirmed that the food items were in the microbiology TB room.

Chemistry:

39. Based on surveyor review of patient final reports and interview with the lab supervisor, it was determined that patient test reports did not include the identity of the "PSA" assay used, as required by the manufacturer of the test kit. The procedure manual indicated that reports from the laboratory to the physician must include the identity of the PSA methodology, i.e. the Centaur XP chemluminescense. The supervisor indicated that he was not aware this information was required on patient final reports.

The following are violations of 19a-36-D35(c) Responsibilities of Director.

40. Based on surveyor record review of the pathology work area and confirmed by interview with the pathologist, it was determined that the laboratory did not have a system in place to track histopathology slides that are hand carried from the main hospital laboratory and read at Tully Health Center. The findings include:
    a. At the time of inspection on March 18, 2009, the pathologist confirmed that histopathology slides are hand carried from Stamford Hospital and read at Tully Health Center. The laboratory does not have a tracking system in place to identify which slides are read at Tully Health Center.

41. Based on surveyor record review of the histopathology final report and confirmed by interview with the pathologist, it was determined that the final report did not include the name and address of the laboratory performing the test. The findings include:
    a. At the time of inspection on March 18, 2009, a review of the final histopathology report revealed that it did not include the name and address of the laboratory which performed the test. The pathologist confirmed that only the three initials "SCT" appeared on the final report for location when testing is performed at Tully Health Center.

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The following is a violation of the Connecticut General Statutes Section 46a-153.

42. Based on review of the facility documentation for the recording of each case of physical restraint usage for the period of 6/1/08 through 12/30/08 identified that the facility failed to include complete information including the consistent documentation of behaviors that necessitated the use of restraint, the type of restraint utilized and restraint alternatives. Additionally, review of restraint documentation dated 12/17/08 reflected that Patient #1 was placed in a posey vest restraint at 12:21 AM, however, review of Patient #1's clinical record identified that the patient was placed in 4 point soft restraints in addition to the vest restraint. This information failed to be recorded on the hospital restraint documentation.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2)(B) and/or (4)(A) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (i) General (6).

43. * Based on review of the clinical record, facility policy and interviews, the facility failed to ensure that anesthesia conducted an appropriate time out prior to the administration of a nerve block. The findings include the following:
    a. Review of the clinical record indicated that Patient #36 was admitted on 12/4/08 for a left shoulder arthroscopy. Review of the anesthesia record indicated that the patient received an interscalene block prior to surgery. The note further identified that the block had inadvertently been placed in the right shoulder. Interview with Anesthesiologist # 1 on 3/20/09 at 10:00 AM indicated that he/she conducted the "time out" by himself. Anesthesiologist #1 indicated that he/she usually exposes the patient's shoulder on the side the block is to be placed then gathers his/her equipment. Anesthesiologist # 1 indicated that he/she turned back to the table and placed the block in the exposed shoulder. Interview with RN #8 on 3/20/09 at 9:30 AM indicated that when the patient entered the OR, it was discovered he/she had undergarments on that needed to be removed and subsequently his/her johnnie coat had been removed and both shoulders were exposed. RN #8 and Anesthesiologist # 1 both indicated that the site marking for the "correct" site was located on the lower aspect of the upper arm near the elbow instead of near the shoulder. Review of the facility policy indicated that site marking should be placed over or as close to the surgical site so it would be visible after the patient is draped.

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FLIS Independent Nurse Consultant Guidelines

Relationship between Independent Nurse Consultant (INC) and DPH includes:

- An INC is utilized as a component of DPH's regulatory remedy process. An INC may be agreed upon as a part of a Consent Order between the institution and the Department when significant care and service issues are identified.
- The INC has a fiduciary or special relationship of trust, confidence and responsibility with the Department.
- The INC's responsibilities include:
  - Reporting to the Department issues and concerns regarding quality of care and services being provided by the institution.
  - Monitoring the institution's plan of correction to rectify deficiencies and violations of federal/state laws and regulations. Reports to Department positive and negative issues related to said oversight.
  - Assessing administration's ability to manage and the care/services being provided by staff.
  - Weekly reporting to the Department of issues identified, plans to address noncompliance and remediation efforts of the institution.

Relationship between INC and the Institution:

- The INC maintains a professional and objective relationship with the institutional staff. The INC is a consultant, not an employee of the institution. The INC exercises independent judgment and initiative to determine how to fully address and complete her/his responsibilities. The institution does not direct or supervise the INC but must cooperate with and respond to requests of the INC related to her fulfilling her/his duties.
- The INC's responsibilities include:
  - Assessment of staff in carrying out their roles of administration, supervision and education.
  - Assessment of institution's compliance with federal/state laws and regulations.
  - Recommendations to institutional administration regarding staff performance.
  - Monitoring of care/services being provided.
  - Assists staff with plans of action to enhance care and services within the institution.
  - Recommendation of staff changes based on observations and regulatory issues.
  - Weekly reports to the institution re: assessments, issues identified, and monitoring of plans of correction.
  - Promotes staff growth and accountability.
  - May present some inservices but primary function is to develop facility resources to function independently.
  - Educates staff regarding federal/state laws and regulations.